Boston Scientific
Advancing science for life™

WATCHMAN FLX™ Pro
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

WATCHMAN FLX Pro Overview

Proven Performance. Optimized for Healing.

WATCHMAN FLX Pro was built on a history of innovation and proven results

2015
FDA Approval

2020
FDA Approval

2023
FDA Approval

WATCHMAN™

2002
PILOT

2005
PROTECT AF

2010
PREVAIL

WATCHMAN FLX™

2018
PINNACLE FLX

WATCHMAN FLX™ Pro

2023
HEAL-LAA
Post-Market Study

2024
Monotherapy Study

300,000+
Patients treated

20 years
Clinical & Real-World Experience

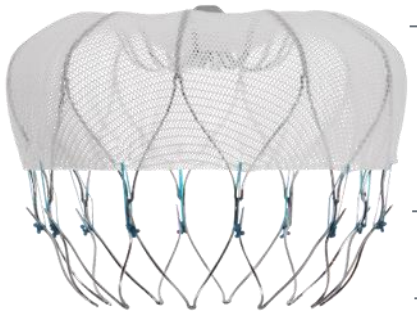
10+
Clinical Trials

WATCHMAN is the most studied, most implanted LAAC device in the world[1]

1. Kar, S., et al, Circulation, 2021.

WATCHMAN FLX™ was a leap forward in safety, simplicity and seal for LAAC

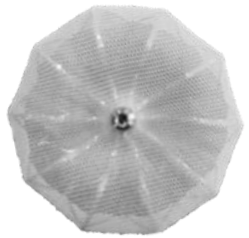
WATCHMAN™



Partial recapture only

Single-row anchors

Open end



10 strut frame

Treatment range 16.8 – 30.5 mm appendages

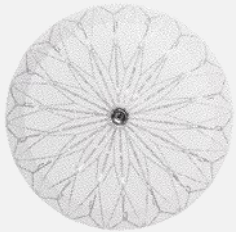
WATCHMAN FLX™

Full recapture and redeployment

Dual-row precision anchors

Closed end

18 strut frame



Fully-Rounded WATCHMAN FLX Ball

Treatment range 14.0 – 31.5 mm appendages

PINNACLE FLX Trial Results[1]

0.5%
Event Rate

98.8%
Procedural Success

89.5%
Complete Seal (No leak) At 12-Months

WATCHMAN FLX is a proven platform that set the standard in LAAC[1]

1. Kar, S., et al, Circulation, 2021.

WATCHMAN FLX™ Pro Takes the Next Step Forward to Advance Safety and Performance

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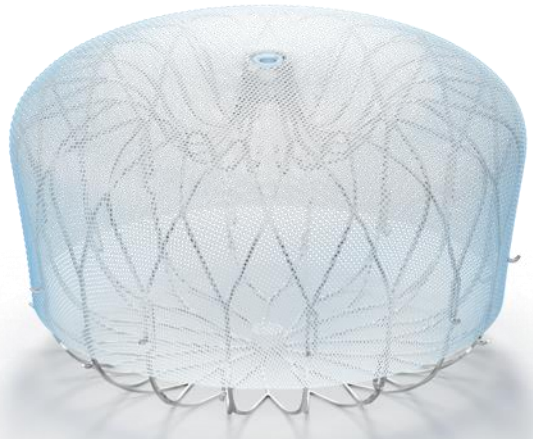
WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Featuring
HEMOCOAT™
Technology

Design Goals:

Reduce Device Related Thrombus	Post-Approval Monotherapy Study	Reduce Untreatable LAAs	Improve Seal Performance

Current Data

~2-4% @ 12mo.[1,2]	~8% Major Bleeding @ 12mo.[1]	2.5% Screen Fails & Aborts[3]	90% Complete Seal at 12 mo.[1]

SH-1561607-AC 1. Kar S, et al. Circulation. 2021 2. Holmes et al. JACC 2019 3. Data sourced from database maintained by WATCHMAN Sales

WATCHMAN FLX Pro Device

Built on the proven performance of WATCHMAN FLX, WATCHMAN FLX Pro promotes faster, more complete endothelialization.[1]

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WATCHMAN FLX™ Pro

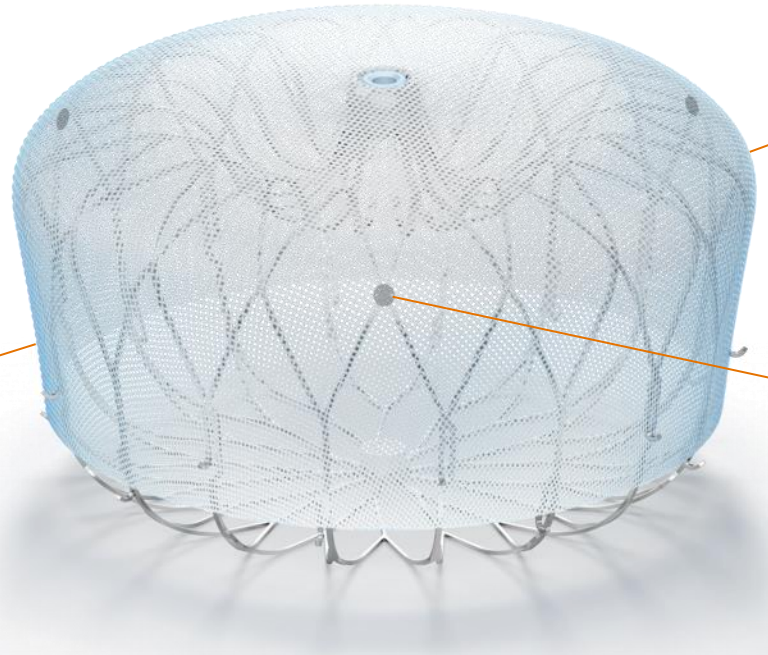
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

WATCHMAN FLX platform

with proven safety & procedural performance[2]

New 40mm device

to treat even larger anatomies



HEMOCOAT™ Technology

to promote faster, more complete endothelialization

New radiopaque markers

help position and anchor device with a new level of visual accuracy

WATCHMAN FLX Pro is designed to enhance the healing process and optimize LAAC for more patients

1. . Saliba, W. et al. JACC EP, May 2023 2. Kar, S., et al, Circulation, 2021.

WATCHMAN FLX™ Pro Featuring HEMOCOAT™ Technology

HEMOCOAT Technology is a durable, thromboresistant coating that results in less inflammation and leads to faster, more complete endothelialization.[1]

Established

20 Million+
Implants Globally[2]

PVDF-HFP has a long history of safe use on permanently implanted, blood-contacting medical devices[3]

Stable

Non-active, non-eluting

Durable, thin coating encapsulates healing surface of device, maintains pore size and mechanical performance of WATCHMAN FLX platform (<1µm)[4]

Demonstrated

Impressive performance in challenging preclinical model[1]

Testing in pre-clinical model has shown remarkable results for faster, more controlled healing[1]

1. Saliba, W. et al. JACC EP, May 2023 2. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006
3. Wagner et al., Biomaterials Science: An Introduction to Materials in Medicine, 4th Edition, 2020 4. Boston Scientific Data on File..

WATCHMAN FLX™ Pro Featuring HEMOCOAT™ Technology

Enhanced healing demonstrated in pre-clinical model with no anticoagulation

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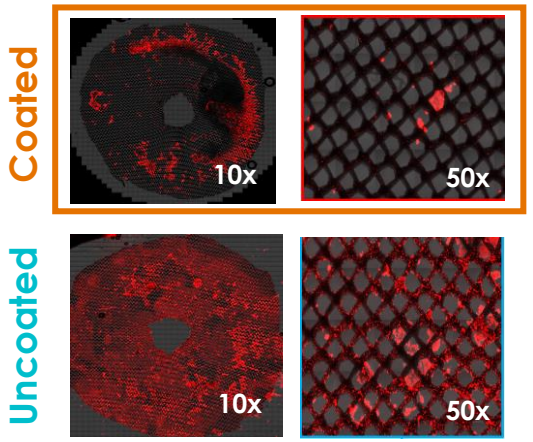
Less Platelet Binding

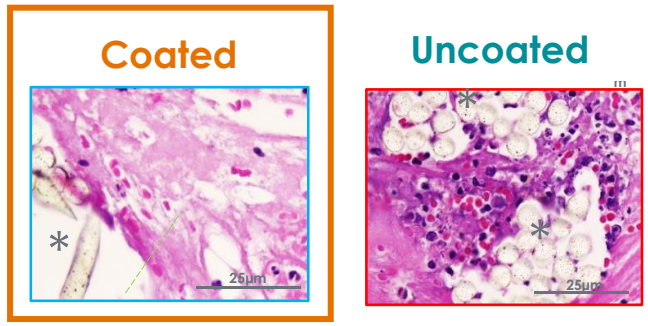


>25%

Reduction in platelet binding.[1]

*In a 3 hour human blood flow loop.
Devices stained Red for platelet deposition.

Less Inflammation

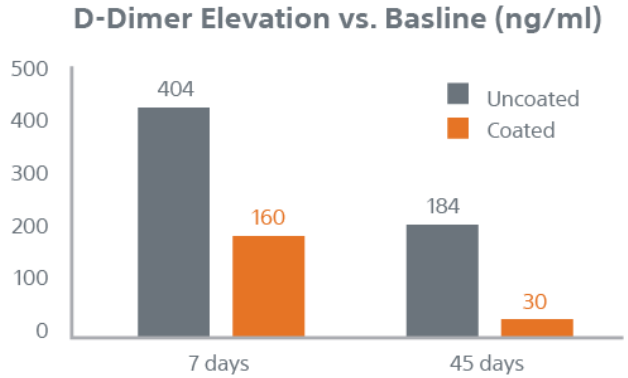


~85%

Reduction in inflammation at 3 days.[1]

Purple = greater inflammation around fabric knots in uncoated group

Less Thrombus



~70%

Reduction in thrombus at 14 days.[1]

*In a challenged canine model, with no anticoagulation.

1. Saliba, W. et al. JACC EP, May 2023.

WATCHMAN FLX™ Pro Featuring HEMOCOAT™ Technology

Enhanced healing demonstrated in pre-clinical model with no anticoagulation

HEMOCOAT™ Technology led to faster, more complete endothelialization in pre-clinical studies.

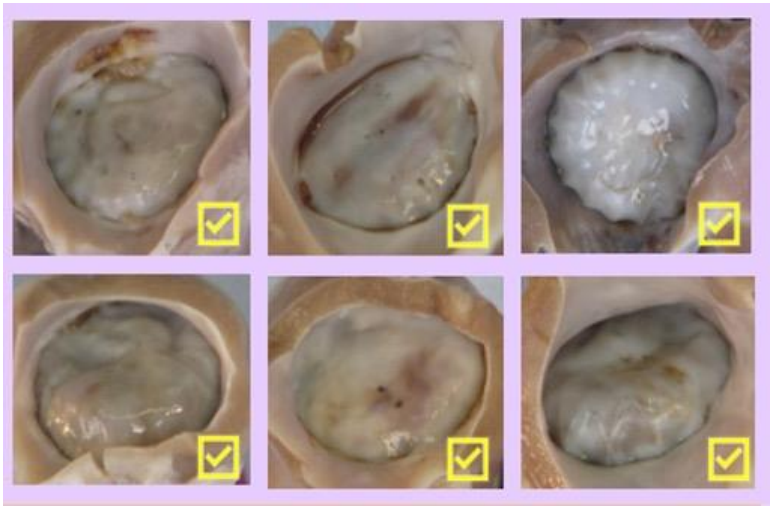
WATCHMAN FLX™ Pro
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

~50%

Increase in endothelial coverage at 45 days.[1]

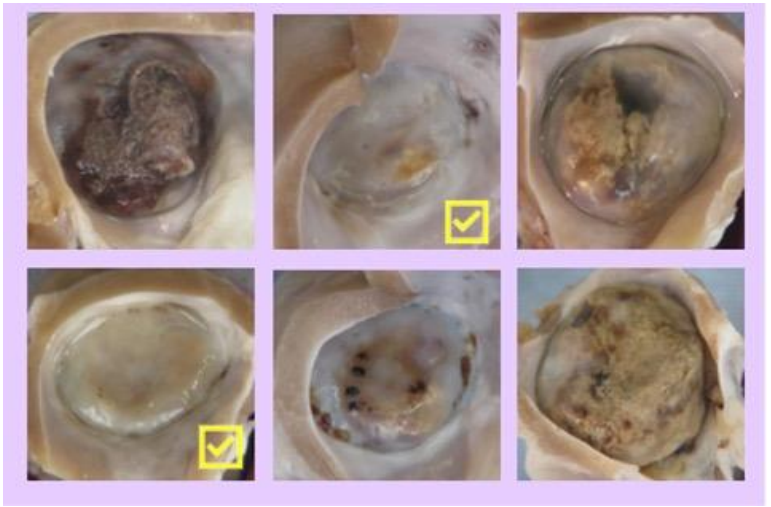
COATED

6/6 exhibit complete coverage/healing at 45 days



UNCOATED

2/6 exhibit complete coverage/healing at 45 days



*Challenged non-anticoagulated canine model. Not representative of clinical results

1. Saliba, W. et al. Moderated Poster Presentation, ESC

Early evidence has given confidence to initiate a Post Approval Monotherapy study

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Faster, more controlled healing with WATCHMAN FLX™ Pro gives promise for a future with a less aggressive post-implant drug regimen

Post Approval Monotherapy Study

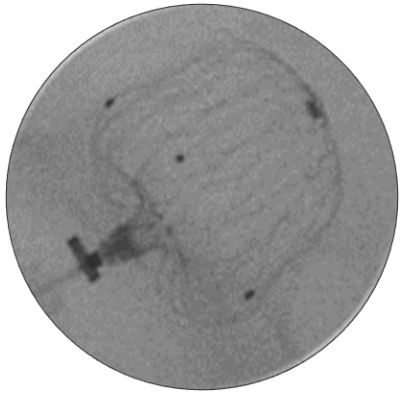
Current LAAC Indication
N=1,500

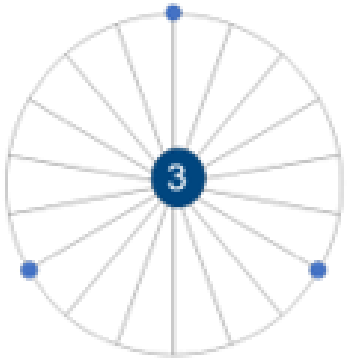
3-Arm Post-Implant Drug Regimen
Control | SAPT | Low-Dose DOAC

1-Year Composite Endpoint
All-cause death | Stroke | Systemic Embolism | Major Bleeding

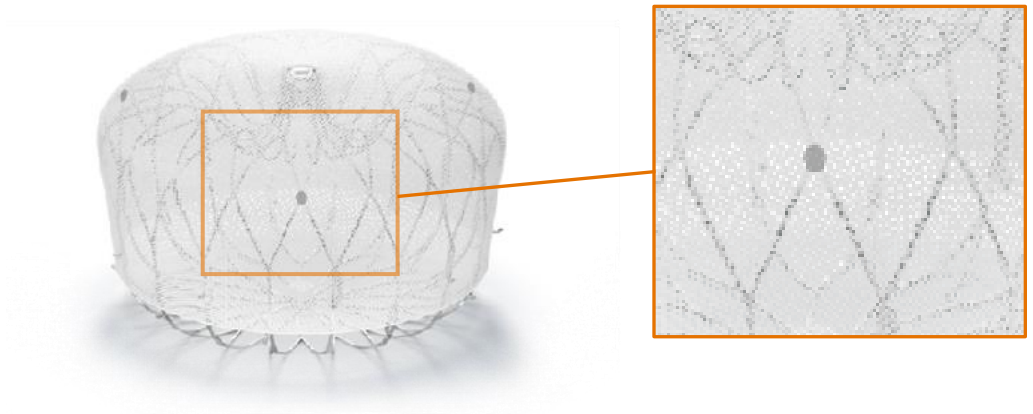
Three New Radiopaque Markers

Next Level Visibility





Three markers, evenly spaced circumferentially



Located at the plane of maximum diameter

Positioned for optimal sealing performance

Designed for increased visibility and performance during procedure

Three New Radiopaque Markers

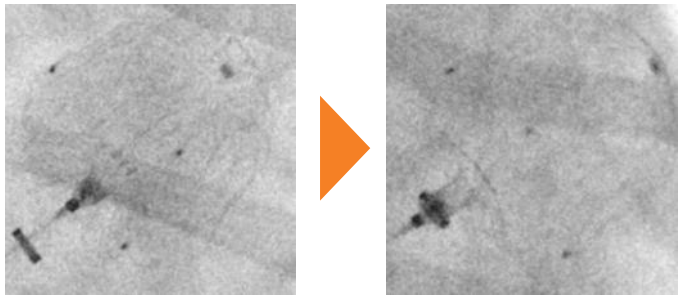
Next Level Visibility for optimized device placement

Three new radiopaque markers help position and anchor the device with a new level of visual accuracy.

Enhance Deployment Precision

57% increased visibility for more accurate device positioning[1]

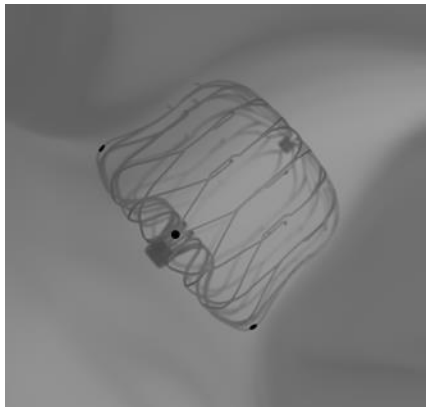
Ensure Device Stability



Failed tug test

Improved assessment of device anchoring when performing tug test

Enable Confident Release

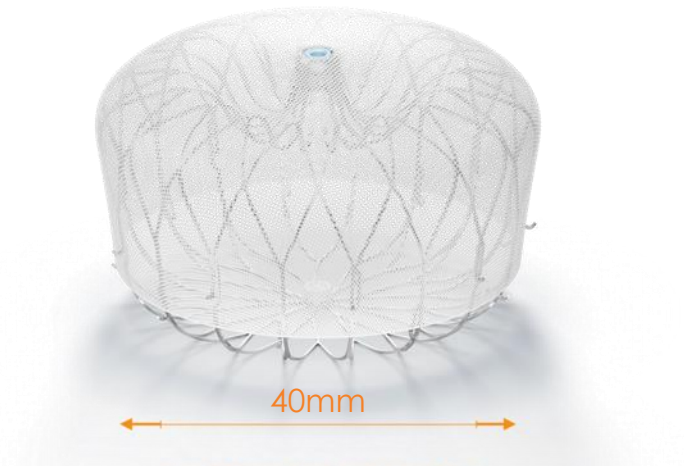


Improved visualization of device orientation and alignment

1. Bench study performed under CT by Boston Scientific. Data on file.

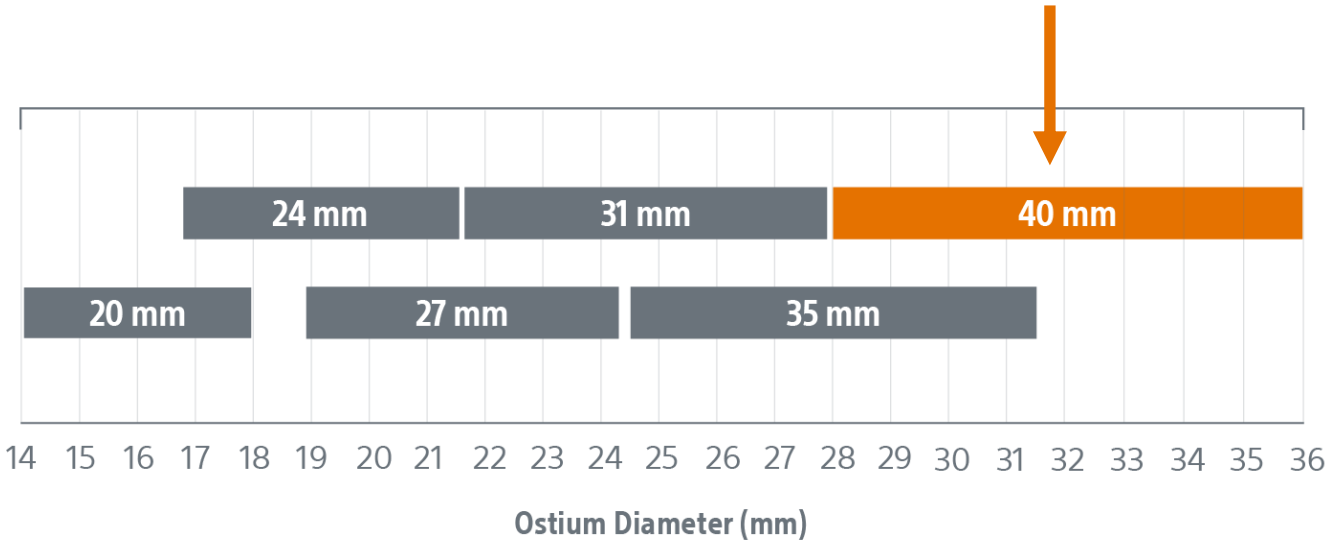
First-Ever 40mm Device to Treat Even Larger Anatomies

New 40mm device



- Same Performance[1]
- Same Compression Range (10-30%)[1]
- Same Depth Requirement[1]

25% Larger Size Range



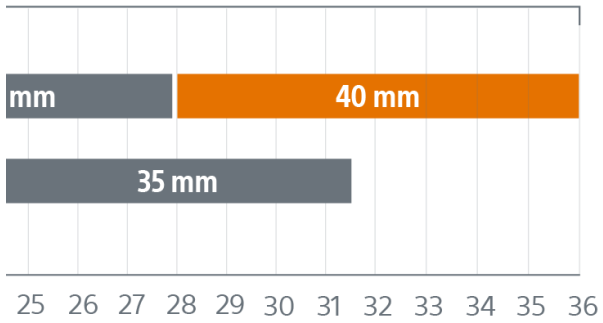
SH-1561607-AC 1. Boston Scientific. Data on file.

Larger 40mm Device to Treat More Patients

Close with Confidence

Expand your Treatable Population by up to ~6%

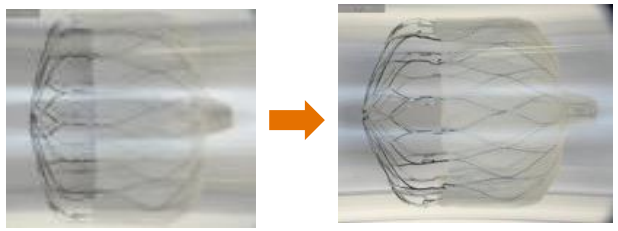
Previously untreatable



~6%

LAAs with ostial diameter larger than 31.5mm[1]

Improve implants with suboptimal 35 mm result

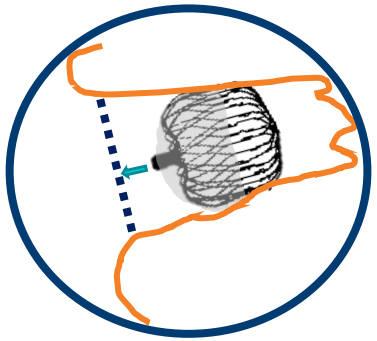


35mm @ 10% compression

40mm @ 21% compression

~18%

35mm implanted with less than desired compression[2]



~12%

35mm implanted more distal than desired to achieve compression[3]

SH-1561607-AC 1. BSC Data on File 2. BSC Data on File 3. BSC Data on File

WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Built on the proven performance of the WATCHMAN FLX device[1],

WATCHMAN FLX Pro featuring HEMOCOAT™ Technology is designed to enhance the healing process and optimize the therapy for more patients.

 SH-1561607-AC 1. Kar, S., et al, Circulation, 2021

Brief Summary

WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE:** WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage. **INDICATIONS FOR USE:** The WATCHMAN FLX Pro Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who: Are at increased risk for stroke and systemic embolism based on CHA_2 DS_2-VASc[1] scores and are recommended for anticoagulation therapy; • Are deemed by their physicians to be suitable for anticoagulation therapy; and • Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy. **CONTRAINDICATIONS:** Do not use the WATCHMAN FLX Pro Device if: Intracardiac thrombus is present. • An atrial septal defect repair or closure device is present. • A patent foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a Closure Device (see Step 7 *in the IFU*). • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN FLX Pro Device is contraindicated. • Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. • There are contraindications to the use of anticoagulation therapy, aspirin, or $P2Y_{12}$ inhibitor. **WARNINGS:** Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program. • For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient. • This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication. • Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium. • Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15 in the IFU) are satisfied to avoid suboptimal results. • Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period. • If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE. • Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail. • Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised. **PRECAUTIONS:** The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. • The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device. • Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures. • Use caution when introducing the Delivery System to prevent damage to cardiac structures. • To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Pro Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath. • If using a power injector, the maximum pressure should not exceed 690 kPa (100 psi). • Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.
ADVERSE EVENTS: Potential adverse events which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism • Airway trauma • Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication • Altered mental status • Anemia requiring transfusion • Anesthesia risks • Angina • Anoxic encephalopathy • Arrhythmias • Atrial septal defect • Bruising, hematoma, or seroma near the catheter insertion site • Cardiac perforation • Chest pain/discomfort • Confusion post-procedure • Congestive heart failure • Contrast-related nephropathy • Cranial bleed • Death • Decreased hemoglobin • Deep vein thrombosis • Device embolism • Device fracture • Device thrombosis • Edema • Embolism • Excessive bleeding • Fever • Fistula • Groin pain • Groin puncture bleed • Hematuria • Hemoptysis • Hypotension • Hypoxia • Improper wound healing • Inability to reposition, recapture, or retrieve the device • Infection/pneumonia • Interatrial septum thrombus • Intratracheal bleeding • Major bleeding requiring transfusion • Misplacement of the device/improper seal of the appendage/movement of device from appendage wall • Myocardial erosion • Myocardial infarction • Nausea • Oral bleeding • Pericardial effusion/tamponade • Pleural effusion • Prolonged bleeding from a laceration • Pseudoaneurysm • Pulmonary edema • Radiation injury • Renal failure • Respiratory insufficiency/failure • Stroke – Hemorrhagic • Stroke – Ischemic • Surgical removal of the device • TEE complications
(e.g., throat pain, bleeding, esophageal trauma) • Thrombocytopenia • Thrombosis • Transient ischemic attack (TIA) • Valvular or vascular damage • Vasovagal reactions. There may be other potential adverse events that are unforeseen at this time. 97097061 A.1